

## **REMARKS**

In the Office Action dated July 24, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 and §372, alleging that the subject matter defined by the claims of the present invention represents the following nine separate and distinct inventions:

- I. Claims 1-5, drawn to a method for facilitating the termination of cell signaling by a cytokine by promoting the interaction of a SOCS-box-containing peptide and another molecule.
- II. Claims 6 and 7, drawn to an agonist or antagonist of cytokine-mediated cell signaling.
- III. Claims 8-10, drawn to a method of modulating SOCS-associated functions.
- IV. Claim 11, drawn to the use of compounds in the manufacture of a medicament.
- V. Claim 12, drawn to a genetically modified animal.
- VI. Claims 13-15, drawn to a method of targeting a protein in a cell for degradation using a polypeptide.
- VII. Claims 16-19, drawn to a method of targeting a protein in a cell for degradation using a polynucleotide.
- VIII. Claims 20, and 23, drawn to a method identifying agonists or antagonists, which inhibit protein degradation.
- IX. Claims 21 and 22, drawn to an antagonist, which inhibits protein degradation.

The Examiner alleges that the inventions listed as Groups I-IX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the groups lack the same or corresponding special technical feature. Specifically, the Examiner contends that the special technical feature of Group I is a method for facilitating the termination of cell signaling; the special technical feature of Group II is an agonist or antagonist; the special technical feature of Group III is a method of modulating SOCS-associated functions; the special technical feature

of Group IV is the use of compounds to manufacture a medicament; the special technical feature of Group V is a genetically modified animal; the special technical feature of Group VI is a method of targeting a protein using a polypeptide; the special technical feature of Group VII is a method of targeting a protein using a polynucleotide; the special technical feature of Group VIII is a method of identifying agonists and antagonists; and the special technical feature of Group IX is an antagonist, which inhibits protein degradation. The Examiner contends that the special technical features of the Groups are not the same and do not correspond to one another. In addition, the Examiner contends that the products of Groups II, V and IX are structurally and functionally distinct, and that the methods of Group I, III, IV and VI-VIII require different method steps and reagents for achieving different goals.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group VIII, claims 20 and 23, drawn to a method for identifying agonists or antagonists, which inhibit protein degradation, for continued prosecution. Applicants reserve the right to file one or more divisional applications to pursue the non-elected embodiments. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution

which each of the claimed inventions, considered as a whole, makes over the prior art."

(Emphasis added.)

Applicants submit that Groups I-IX are not distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application. More specifically, the present inventors uniquely recognized that the SOCS box in proteins facilitate the presentation of proteins bound to the SOCS box to the ubiquitination and/or proteasomal compartments. Generally, the presentation of proteins to these compartments requires elongin B and/or elongin C. Thus, according to the present invention, the SOCS-box containing proteins form a family of adapter proteins which terminate cell signaling by targeting critical molecules for intracellular degradation. Therefore, the methods and compositions of Groups I-IX are all premised on the above unique discovery. Specifically, Claims 1-5 (Group I) are directed to methods of facilitating the termination of cell signaling by a cytokine by promoting the interaction of a SOCS-box-containing peptide and another molecule. Claims 6-7 (Group II) are drawn to an agonist or antagonist of cytokine-mediated cell signaling, which agonist or antagonist promotes or prevents, e.g., the formation of a complex between a SOCS-box containing protein and an elongin protein. Claims 8-10 (Group III) are drawn to a method of modulating SOCS-associated functions. Claim 11 (Group IV) is drawn to the use of a SOCS-box containing protein, an elongin protein, or the antagonist or agonist of Group IV in the manufacture of a medicament. Claim 12 (Group V) is drawn to a genetically modified animal which contains mutation in genetic material coding for a SOCS-box containing protein such that, e.g., the mutant SOCS-box containing protein is unable to interact with an elongin protein. Claims 13-17 are drawn to methods of targeting a protein in a cell for degradation using a polypeptide (Group VI) or a polynucleotide (Group VII). Claims 20-23 are drawn to a method

identifying agonists or antagonists (Group VIII), which inhibit protein degradation, as well as an antagonists identified (Group IX).

The Examiner has not commented on claims 24-25, which are drawn to an agonist identified by the method of claim 23. These claims were added by way of the Preliminary Amendment dated June 21, 2001.

Clearly, Claims 1-25 are linked to each other under the single inventive concept that the SOCS-box containing proteins form a family of adapter proteins which terminate cell signaling by targeting critical molecules for intracellular degradation. Applicants respectfully submit that Groups I-IX are merely different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Accordingly, it is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, i.e., claims 1-25.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Frank S. DiGiglio  
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343

FSD/XZ/rjl